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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/646,539 | 08/22/2003 | Jay Douglas Audett | ARC3254R1/A5033 | 9721 |
| 27777 | 7590 | 10/28/2005 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | CHANG, VICTOR S | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1771 | |

DATE MAILED: 10/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,539

Applicant(s)

AUDETT, JAY DOUGLAS

Examiner

Victor S. Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/9/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of species in the reply filed on 9/14/2005 is acknowledged. However, the reply is not fully responsive to the prior Office Action because of the following omission(s) or matter(s):

First, the Examiner repeats the species election as follows:

I. Outer layer

Please elect one species as set forth in claims 2 and 3.

II. Tie layer structure

(1) a single layer, as set forth in claims 1, 7, 8 and 12;

If a single layer structure is elected, please also elect one species of material as set forth in claims 5 and 6;

(2) a multilaminate layer, as set forth in claims 13 and 15;

III. Reservoir

(1) as set forth in claims 1 and 13 (embodiment without reservoir);

(2) as set forth in claims 7, 12, 14 and 15 (tie layer comprising a secondary drug-containing reservoir);

(3) as set forth in claim 8 (tie layer comprising an antagonist-containing reservoir);

IV. Release controlling means

(1) outer layer, and not releasable through base layer, as set forth in claims 9-11;

(2) base layer, as set forth in claims 12 and 17.

Second, in response to Applicant's reply, the Examiner notes:

1) Applicant's election of *claim 3* for Species Category I is non-responsive, because claim 3 recites multiple species, e.g., spun-bonded, spun-laced, rayon, wood-pulp, etc. Further, spun-bonded or spun-laced, etc., also encompass various materials, as recited in claim 4. Applicant is advised that a proper election must be a *single species* in this category. It should be also noted that the general test as to when claims are restrictable to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first. See MPEP 806.04(f).

2) Applicant's election of multilaminate tie layer for Species Category II is acknowledged. However, the Examiner notes that such an election is directed to independent claims 13-16 alone. Applicant's argument "claims 1, 7, 8, 12 and 5-6 do not preclude having a multilaminate tie layer and therefore are generic. Further claim 6 is independent on claim 5 and therefore claim 5 is generic to claim 6" (Remarks, page 2) is erroneous, because *independent* claims 1, 7, 8 and 12 are clearly directed to an embodiment in which the tie layer is a single layer structure, as shown in Fig. 1, which is in direct contact with the outer and base layers (paragraph 00037), as opposed to an alternative independent and distinct embodiment, as shown in Fig. 2, as a multilaminate

(paragraph 00016). In particular, it should also be noted that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 f.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, it should also be noted that since claims 1, 7, 8, 12 and 13 are *independent* claims are directed to structurally *independent and distinct embodiments*, and modifying limitations of their respective dependent claims are not shared, i.e., it is not seen how they can be generic to each other. As such, the Examiner asserts that the embodiments in claims 1-12 are precluded by the election of multilaminate tie layer.

3) With respect to Species Category III, Applicant's response electing a secondary reservoir containing an antagonist, as seen in claim 8, is acknowledged. Since species "antagonist" reads on genus "drug", the Examiner agrees that claims 7, 12, 14 and 15 are also elected. However, Applicant's statement "... claim 1, 13 ... all refer to a secondary reservoir and are generic to claim 8" (Remarks, page 2) is incorrect, because nowhere the claimed scope of independent claims 1 and 13 include a secondary reservoir. It should also be noted that if Applicant considers the secondary reservoir as an essential and critical element of instant invention, the absence such limitation in independent claims 1 and 13 renders them not enabling under 35 USC 112, first paragraph.

4) With respect to Species Category IV, Applicant's reply electing outer layer controlling release of an antagonist, claims 9-11, is acknowledged.

In summary, claims 14-16 are mutually elected species. Further, since claims 1-13 and 17 are withdrawn from further consideration, and the non-responsive election of

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claim 3 in Species Category I does not affect the mutually elected claims, this application is ready for prosecution. Nevertheless, Applicant may wish to clarify the species election for Category I in the next reply, if these claims are to be amended.

Finally, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The limitation of elected species "outer layer is an antagonist release rate controlling means and antagonist is not releasable through the base layer" is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

More particularly, neither claim 14, nor its parent independent claim 13, recites the limitation of elected species, and renders the scope of invention incomplete. One of ordinary skill in the art would not know how the invention is enabled. Appropriate correction is required.

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4. Claims 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

More particularly, while the specification discloses an embodiment of transdermal system having a multilaminate tie layer and a base layer as a drug release rate controlling means (paragraph 00029), nowhere in the specification is there an embodiment of an multilaminate tie layer being incorporated with the limitation of elected species "outer layer is an antagonist release rate controlling means and antagonist is not releasable through the base layer". As such, it appears that the scope of elected invention is new matter.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 13-16 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility.

It is noted that the instant invention is used as a transdermal drug delivery system. However, the limitation of elected species "outer layer is an antagonist release rate controlling means and antagonist is not releasable through the base layer" appears rendering the instant invention inoperable, because it prevents the drug from being

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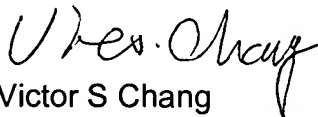
delivered through the base layer to the skin. As such, in the absence of any disclosure as to how the drug can be transdermally delivered through the outer layer, which is facing away from the skin and also segregated by the base layer, it appears that the instant invention is inoperative and lacks utility.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Victor S Chang
Examiner
Art Unit 1771

10/26/2005